

1 0 2006

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Brian Barrett
ELI LILLY AND COMPANY
PATENT DIVISION/BPB,
LILLY CORPORATE CENTER
INDIANAPOLIS IN 46285

In Re: Patent Term Extension

Application for U.S. Patent No. RE 37,806

Dear Mr. Barrett:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. RE 37,806 for a period of 389 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/efault.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery Fries Senior Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

Office of Regulatory Policy HFD - 13

5600 Fishers Lane Rockville, MD 20857

Attention: Claudia Grillo

RE: XIGRIS® (drotrecogin alpha) FDA Docket No.: 02E-0255

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : RE 37,806

(45) REISSUED : July 23, 2002

(75) INVENTOR : Brian W. Grinnel

(73) PATENT OWNER : Eli Lilly and Company

(95) PRODUCT : XIGRIS® (drotrecogin alpha)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. RE 37,806 based upon the regulatory review of the product XIGRIS® (drotrecogin alpha) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 389 days

from October 28, 2014, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the United States Patent and Trademark Office to be affixed this <u>9th day</u> of <u>February 2006</u>.

Jon W Duda

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office